PATIENT GROUP DIRECTION (PGD)

For the supply of Ulipristal Acetate

Version:	7
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Approved by:	Trudi Grant, Director of Public Health
Date issued:	January 2023
Review date:	January 2025

SOMERSET

PATIENT GROUP DIRECTION (PGD)

FOR: The supply of Ulipristal Acetate

VERSION CONTROL

Document Status:	Approved
Version:	7

Document Change History		
Version	**Date**	**Comments**
1	06/03/2018	Catherine Falconer first draft
2	19/03/2018	Michelle Hawkes amendments
3	15/05/18	Amendments to include decision making algorithm
4	31/05/18	Amendments advised by Rebecca Myers and Michelle Hawkes
5	23/02/2021	Review and update by Michelle Hawkes
6	21/11/2022	Review and update by Michelle Hawkes. Reviewed against new national PGD template.
7	04/01/2023	Anne Cole amendments

Author	Catherine Falconer
Document reference	
Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations' PGD governance system. The organisation's governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.	

PATIENT GROUP DIRECTION (PGD) FOR

Drug: Ulipristal Acetate 30mg tablet
Condition: Adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists

You must be authorised by name, under the current version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly. Individuals aged 12 to 24 years requiring emergency hormonal post-coital contraception (EHC) within 120 hours of unprotected sexual intercourse (UPSI) or failed contraception
2.	**Inclusion criteria**	Individuals including children aged 12 years and over where: • No contraceptive method was used, *or* • A contraceptive method is known to have failed, or • A contraceptive method is suspected of failure, or • A 'pill error' has occurred where emergency contraception is indicated (Refer to Faculty of Family Planning and Reproductive Health Care (FFPRHC) guidance) • For choice of emergency contraceptive method please refer to decision making algorithm in appendix 1 **And** *all* the following criteria are met: • No contraindications to the medication • The individual had UPSI within the previous 120 hours; • Ulipristal acetate is the most appropriate treatment; • The individual has taken EHC on no more than one previous occasion in the current menstrual cycle; • The individual has received ulipristal but has vomited within 3 hours of the dose (provided the repeat dose will be taken within 120 hours of UPSI); • Valid consent from patient or person with parental responsibility has been obtained; • If under the age of 16 years, meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence'). Discussion with the young person should explore the following issues:

		1) Whether the individual is sufficiently mature to understand the advice given; 2) Advice and encouragement to discuss the situation with parents/guardian; 3) The effect on physical/mental health if advice/treatment is withheld; 4) Whether supply of EHC is in the best interest of the individual; • A discussion has occurred with the individual regarding alternative emergency contraception methods - copper intrauterine device (Cu-IUD) - to allow the individual to make an informed choice, and a referral is offered o This should include that insertion of a Cu-IUD is the most effective form of emergency contraception, can be fitted for free up to 120 hours after UPSI, and provides the additional benefit of on-going contraception. If the patient chooses a Cu-IUD, provided the individual has presented within 120 hours of UPSI and there are no other contraindications, ulipristal can still be offered as a precaution (in case the patient misses the appointment) • 21 days or more have elapsed since giving birth
3.	**Exclusion criteria**	• **Aged 25 years or over** (at the discretion of the pharmacist there may be rare exceptions to this based on concerns about the ability of the patient to pay for over the counter EHC or seek help in time from another provider – see section 5). • **Informed consent not given.** • **Any UPSI over 120 hours ago** in this cycle. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours). • **Known pregnancy** (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI). • **Less than 21 days after childbirth.** • **Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).** • **Known hypersensitivity to the active ingredient or to any component of the product** – see Summary of Product Characteristics

		• **Vomiting more than 3 hours after** ingesting ulipristal - If the individual has received ulipristal but has vomited *more* than 3 hours after the dose was taken then they do not need to take a repeat dose • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • **Lactose and galactose intolerance** • **Lapp lactase deficiency or glucose-galactose malabsorption** • **Unexplained vaginal bleeding** • **Severe liver disease / hepatic dysfunction** • **Porphyric individuals –** Individuals with active acute porphyria • **Bowel disorders** - Individuals suffering from bowel disease / disorders (e.g. crohn's disease, ulcerative colitis etc.) causing malabsorption. Although the use of ulipristal emergency contraception UPA-EC is not contraindicated it may be less effective and so those individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed • **Individuals with uncontrolled/severe asthma treated by oral glucocorticoid** • **Anaphylactic reactions** - Any individual who has had a true anaphylactic reaction to ulipristal, any other progestogen, or any component of ulipristal tablets, or having shown hypersensitivity after previous administration: see SPC for a full list of excipients • **Breast cancer** – Individuals with either current or past breast cancer • **Not face-to-face** - The individual requesting EHC is not present in a face to face consultation (supply under this PGD is not allowed through telephone consultations apart from in exceptional circumstances, for example, the patient is unable to attend due to symptoms of COVID-19). • **Liver enzyme inducing drugs** – EC is contraindicated if there is UPSI or barrier failure during, or in the days following, use of liver-enzyme drugs. Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose of Levonorgestrel. Ulipristal is not recommended for individuals taking enzyme inducing drugs, or within 4 weeks of stopping them

		• **Drugs that increase gastric PH**: antacids, histamine H2 antagonists and proton pump inhibitors • **Training -** Pharmacists who have not completed the Somerset County Council (SCC) approved training (see appendix 2) and do not have a current and completed Declaration of Competence for this service. For individuals **16 years of age and over** and assessed as lacking capacity to consent. For individuals **under the age of 16 years**: • Not meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence') if consent to treatment has not been obtained from a person with parental responsibility for the individual • Issues of child-protection have not been considered For individuals **age 12**: • Where a healthcare professional with expertise in child-protection issues has not been consulted. This should be prior to supply of EHC, although in exceptional circumstances if a child-protection expert is not available then supply can be made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart For individuals **under 12**: • Supply is not available under this PGD. A child protection expert must be contacted, and the patient must be managed according to child protection protocol • If the individual has not yet reached menarche (first menstrual cycle) consider onward referral for further assessment or investigation.
4.	**Cautions / Need for further advice**	• All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. • Ulipristal acetate (UPA-EC) is ineffective if taken after ovulation.

		<u>Pregnancy and Breastfeeding</u> **Pregnancy –** • Ulipiristal should not be taken when suspected or known to be already pregnant – do pregnancy test to check when appropriate • A pregnancy test is advised three weeks after UPSI **Breastfeeding –** • Ulipristal is excreted into breastmilk and the risk to infant is unknown • Do not breastfeed or express milk for storage for 1 week after taking ulipristal • Advise to express and discard milk to maintain lactation **Drug interactions** • The effectiveness of ulipristal may be reduced if an individual woman takes progestogen (including levonorgestrel emergency contraception) in the week prior to and five days following ulipristal. Consider Cu-IUD or levonorgestrel in this circumstance • **Other medications** - Consult current BNF and Stockley's Drug Interactions for any potential interactions • **Child protection -** Consider child protection issues including child sexual exploitation (CSE) risks in all individuals under 18 and the requirement to complete the Somerset CSE screening tool where risk is identified (consult with health professional with extensive experience in child protection); and the mandatory reporting requirement for disclosures of Female Genital Mutilation (FGM) for girls aged under 18 (call non emergency '101' number by close of next working day) • **Safeguarding** – Consider safeguarding issues in all individuals age 18 and over (e.g. individuals with learning disabilities; domestic abuse) • **Contraception** – It must be explained that emergency contraception should not be relied upon as a regular form of contraception and that they should seek advice from their GP / sexual health service for a suitable form of contraception, including the promotion of Long Acting Reversible Contraception (LARC) • **Sexually transmitted infection (STI)** – Explain that UPSI has potentially exposed the patient to an STI – Refer to GP or sexual health service for testing and treatment of STIs

		• **Aged 15 – 24** – Explain that UPSI has potentially exposed the patient to chlamydia. Discuss the need for chlamydia screening and offer a chlamydia screening kit, or refer to sexual health service or GP • **Prevention of STIs** – In addition to the promotion of LARC, pharmacists should highlight the importance of preventing sexually transmitted infections by promoting the use of condoms. For those aged 13-19 this should include promotion of the Somerset C-Card condom distribution scheme • **Missed oral contraceptive pill** – Consult FSRH (2020) guidance • **Guidance regarding different contraception** – Consult the current SPC for all different contraceptive products when dealing with requests for emergency contraception • **Under 13 years of age** – A healthcare professional with extensive expertise in child-protection **MUST** be consulted before supply can be considered. In exceptional circumstances if a child-protection expert is not available then supply can be made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart • **NOTE**: A biological parent may not necessarily have parental responsibility for a child, therefore, may not be legally entitled to give consent for treatment • individual has not yet reached menarche consider onward referral for further assessment or investigation.
5.	**Action if excluded**	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate for example the patient's GP, sexual health service and/or provide them with information about further options. • For individuals aged over 25 years discuss/offer alternative emergency contraceptive method including over the counter purchase or referral to GP or sexual health services • If the individual is aged 25 years or over and there are any concerns about their ability to pay for over the counter EHC or seek help in time from another provider, EHC through the algorithm can be supplied with the Pharmacists discretion.

		• Any child protection, safeguarding and/or child sexual exploitation (CSE) issues must be addressed as per training.
6.	**Action if patient declines**	• If appropriate discuss with patient's GP or relevant specialist • Inform or refer to patient's GP or sexual health service as appropriate • Clearly document decision to decline treatment of the patient or person with parental responsibility
7.	**When further medical advice should be sought**	• Advice should be sought from a doctor or relevant specialist in the following circumstances: o If the patient is excluded from treatment o If the patient fulfils any of the criteria listed under the "Cautions" section that require further medical advice • If the patient is under 13 years of age advice MUST be sought from a healthcare professional with extensive expertise in child-protection issues prior to treatment under this PGD proceeding. In exceptional circumstances if a child-protection expert is not available then supply can be made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart If an adverse reaction does occur, provide immediate treatment and inform a doctor with responsibility for medical care of the individual as soon as possible. Report the reaction to CSM/MHRA using the "Yellow Card" system

PATIENT GROUP DIRECTION (PGD) F O R

Drug: Ulipristal Acetate 30mg tablet
Condition: Adults and children aged over 12 years requiring only emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists

8.	**Drug Details**	
	Name, form and strength of medicine	Ulipristal Acetate 30mg
	Legal Category	Pharmacy Medicine
	Black Triangle Status	None
	Route / method of administration	Oral
	Dosage	One tablet (30mg) as a single dose treatment as soon as is practicable after unprotected sexual intercourse (UPSI). Can be taken at any time during the menstrual cycle, with or without food.
	Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment Medicines should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for

		the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
	Frequency	Once as a single dose treatment, except: • If vomiting occurs within three hours of taking the ulipristal 30mg tablet a second supply of one ulipristal 30mg tablet may be made AND • All inclusion and exclusion criteria still hold
	Duration of treatment	Single dose treatment
	Total dose number to supply / administer	One 30mg tablet *except:* • If vomiting occurs within three hours of the patient taking ulipristal 30mg tablet a repeat supply of a second single 30mg tablet is allowed. • Repeated doses, as separate episodes of care, can be given within the same cycle. Please note: o If within 7 days of previous levonorgestrel emergency contraception (LNG-EC) offer LNG-EC again (not UPA-EC) • If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)
9.	**Identification & management of adverse reactions**	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org or Stockley's Drug Interactions. Refer also to FSRH guidance on drug interactions with hormonal contraception file://rlbuht.lan/userdata/jjenkins/Downloads/drug-interactions-with-hormonal-contraception-5may2022.pdf The following side effects are common with UPA-EC (but may not reflect all reported side effects): • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia)

		• Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
10.	**Reporting procedure of Adverse Reactions**	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record. • All significant events / incidents / near misses occurring in relation to the supply of emergency hormonal contraception under this PGD must be reported to Somerset County Council on the relevant incident form in a timely manner
11.	**Written information and further advice to be provided**	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than

		usual), or if using hormonal contraception which may affect bleeding pattern.
		• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.
		• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
		• Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.
		• Useful contacts for patients include:
		  ○ Sexwise – www.sexwise.org.uk
		  ○ NHS Worth Talking About 0800 282930. Sexual health - NHS (www.nhs.uk)
		  ○ NHS Direct – 111
		  ○ Sexual health services in Somerset www.swishservices.co.uk
		  ○ Downloading the Somerset young people's sexual health app (Swish app)

12.	**Advice/follow up treatment**	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required. • Further contact with other medical professionals, including safeguarding and child protection issues, as well as onward referrals should be managed as per requirements in exclusions/cautions/referral sections
13.	**Referral arrangements**	• **Late period / abnormal bleeding** - Patients should consult a GP, or a relevant specialist service if the patient's next period is seven or more days late or if abnormal bleeding occurs • **Sexually transmitted infections** (STI) - Refer patient to GP, or sexual health service for evaluation / treatment if the presence of sexual transmitted infection (STI) is known or suspected • **Chlamydia screening** – If between aged between 15 and 24 years offer chlamydia screening kit or refer to GP or sexual health service

		• **Lower abdominal pain** - If any lower abdominal pain occurs, the patient should seek further medical evaluation (because the pain may signify an ectopic pregnancy) • **Contraception** – for emergency Cu-IUD fitting and / or ongoing contraceptive needs refer to general practice or SWISH • **Sexual health app** – Pharmacists should make use of the Somerset sexual health app (Swish app) to provide information to patients about other sexual health services available • **Aged over 25 years –** Advise on alternative arrangements for EHC including over the counter purchase or referral to GP or sexual health service.
14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	**Accredited pharmacists in Somerset are to use the PharmOutcomes system for recording purposes.** It is essential to record the following patient information: • Patient's name/address/date of birth and consent • Indications for use • Advice given to patient/carer to (include side effects) • Brand, batch number and expiry date of medicine • Name of medicine / dose/ quantity supplied Additionally the following is to be noted in the patient's record: • For individuals aged under 16: a statement as to the 'Fraser' competence of the individual • For children under 13 years of age: details of the discussion with the safeguarding expert prior to consideration of supply • For individuals with a BMI ≥ 26kg/m^2 or body weight >70kg, this is to be recorded • For individuals aged over 25 years and for whom ulipristal is supplied on the PGD using the discretionary clause, this is to be recorded. • **Records of all individuals receiving treatment with emergency hormonal contraceptives under this PGD need to be kept for clinical audit and medico-legal purposes. Therefore, the pharmacist working under this PGD must record supply of**

		any medication through the PharmOutcomes system. Records should be kept for at least eight years, or for children, until the child is 25 years old • Individuals supplied with medicines or have medicines administered under PGDs are subject to the normal NHS prescription charges and exemptions All emergency hormonal contraception should be stored in accordance with the specifications of this PGD and the SPC. • Document any adverse reactions • Where the child is not accompanied by a person with parental responsibility the name and relationship of the person bringing the child for treatment should be recorded **Serious events / incidents / near misses** - All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported on the relevant incident form in a timely manner
Staff Characteristics		
Professional qualifications		• Pharmacist registered with the General Pharmaceutical Council of Great Britain • Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation • Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions
Specialist competencies or qualifications		• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. • Pharmacists providing this service must have completed the Somerset County Council (SCC) approved training (see appendix 2) and have a current and completed Declaration of Competence for this service. • Individual has undertaken appropriate training for working under PGDs for the supply and

	administration of medicines. Recommended training - eLfH PGD elearning programme • Suggested other training includes: successful completion of a relevant contraception module/course accredited or course endorsed by the FSRH, a university or as advised in the RCN training directory. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
Continued education & training	• It is recommended that pharmacists access additional learning on Child Sexual Exploitation (e.g. NHS choices How to spot CSE) and Female Genital Mutilation (FGM_training_slides) • Individual continued Professional Development
Additional Requirements	• The health care professional is professionally accountable for this work and should be working within his / her competence • The manufacturers Summary of Product Characteristics (SmPC) (available at www.medicines.org.uk) must always be referred to for a more complete overview of the medicine supplied under this PGD • The pharmacist must be authorised by name under the current version of this PGD before working under it • Pharmacists should supervise the client taking the ulipristal particularly if they have concerns (i.e. about frequent requests or that may be being obtained for another person) • The pharmacist must be able to access this PGD when needed

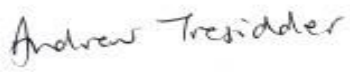
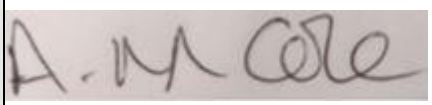
References used in this PGD

- Ulipristal National PGD template V2.0 March 2023 Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception: PGD template last updated November 2022
- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 (Amended March 2000) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines
- DH (2003) NHS code of practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality_-_NHS_Code_of_Practice.pdf
- DH (2004) Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189
- DH (2006) Medicines Matters http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064325
- ellaOne 30mg Product characteristics. Accessed on 5th February 2018. https://www.medicines.org.uk/emc/product/6657

PATIENT GROUP DIRECTION (PGD) FOR:

Drug: Ulipristal Acetate 30mg tablet **Condition:** Adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI) **Professional group:** Registered Pharmacists

This patient group direction must be agreed to and signed by all health care professionals involved in its use. The Somerset County Council should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	

Authorisation	**Signature** **Date**
Nominated GP	 05/01/2023 Dr Andrew Tresidder MBBS Cert Med Ed GMC 2823735
Director of Public Health	 05/01/2023 Prof Trudi Grant, MSc PH, UKPHR, FFPH Director of Public Health Somerset County Council
Senior Pharmaceutical Advisor	 05/01/2023 Anne Cole, BPharm, MSc, FRPharmS
	N/A

Consultant Microbiologist **(for Antibiotics)**	

PATIENT GROUP DIRECTION (PGD) FOR

Drug: Ulipristal Acetate 30mg tablet
Condition: Adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists
Professional Group:

Individual Authorisation

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

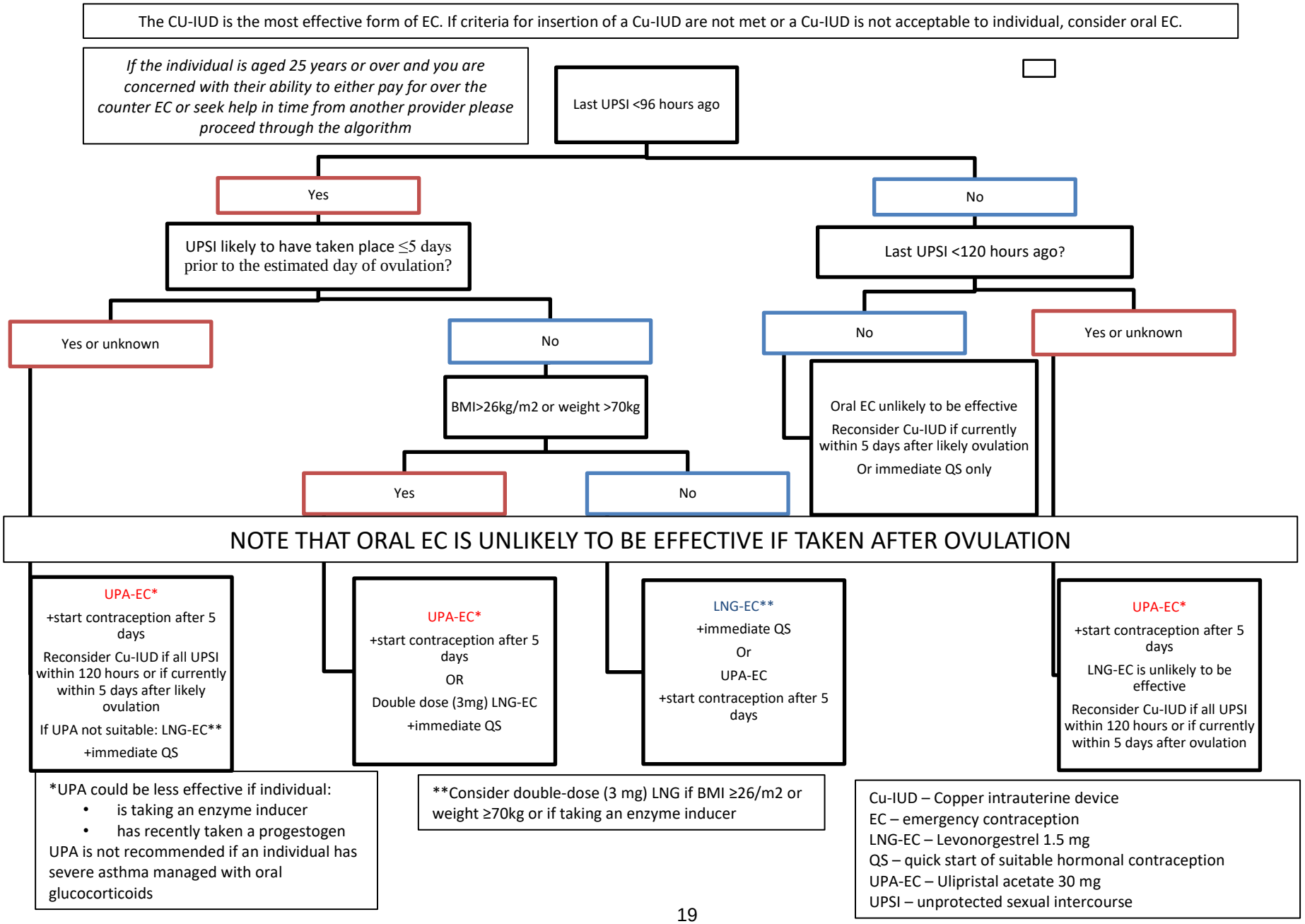
I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

Location:				
Name of Professional	**Professional registration no. (pharmacists only**	**Signature**	**Authorising Manager[1]**	**Date**

Please ensure a copy of this page is kept by the Line Manager.

Pharmacist – please retain signed copy onsite and available for inspection by a Somerset County Council representative on request

Appendix 1: Decision making algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) VS Ulipristal Acetate EC (UPA-EC)



Appendix 2: Mandatory and recommended training to be completed for the pharmacy Emergency contraception Patient Group Directions (PGDs) in Somerset

Format	Programme title	Repeat at least every:
Online workshops	**Somerset LPC and Somerset County Council Emergency contraception, safeguarding and child exploitation** (This is the preferred option - see the LPC bulletin and **website** for the next date and booking details) **Or** **CPPE Emergency contraception**	4 years (mandatory) **Or** 4 years (mandatory)
e-learning	**CPPE Emergency Contraception** **elearning for healthcare Safeguarding adults Level 2** **elearning for healthcare Safeguarding children Level 2** **CPPE Contraception** **elearning for healthcare Patient Group Directions** **CPPE Safeguarding children, young people and adults: level 2 case studies for pharmacy professionals** **CPPE Consultation skills: what good practice looks like**	2 years (mandatory) 2 years (mandatory) 2 years (mandatory) Once (recommended) Once (recommended) Once (recommended) Once (recommended)
e-assessment	**CPPE Emergency contraception** **CPPE Consultation skills for pharmacy practice** **CPPE Contraception**	2 years (mandatory) Once (recommended) Once (recommended)

Complete and sign the **CPPE Declaration of Competence for Emergency contraception** (recommended review at least every 2 years) and allow your data to be shared with PharmOutcomes in **MyCPPE:**